Radiation exposure in relation to the arterial access site used for diagnostic coronary angiography and percutaneous coronary intervention: a systematic review and meta-analysis

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Summary

Background Transradial access for cardiac catheterisation results in lower bleeding and vascular complications than the traditional transfemoral access route. However, the increased radiation exposure potentially associated with transradial access is a possible drawback of this method. Whether transradial access is associated with a clinically significant increase in radiation exposure that outweighs its benefits is unclear. Our aim was therefore to compare radiation exposure between transradial access and transfemoral access for diagnostic coronary angiograms and percutaneous coronary interventions (PCI).

Methods We did a systematic review and meta-analysis of the scientific literature by searching the PubMed, Embase, and Cochrane Library databases with relevant terms, and cross-referencing relevant articles for randomised controlled trials (RCTs) that compared radiation parameters in relation to access site, published from Jan 1, 1989, to June 3, 2014. Three investigators independently sorted the potentially relevant studies, and two others extracted data. We focused on the primary radiation outcomes of fluoroscopy time and kerma-area product, and used meta-regression to assess the changes over time. Secondary outcomes were operator radiation exposure and procedural time. We used both fixed-effects and random-effects models with inverse variance weighting for the main analyses, and we did confirmatory analyses for observational studies.

Findings Of 1252 records identified, we obtained data from 24 published RCTs for 19 328 patients. Our primary analyses showed that transradial access was associated with a small but significant increase in fluoroscopy time for diagnostic coronary angiograms (weighted mean difference [WMD], fixed effect: 1·04 min, 95% CI 0·84–1·24; p<0·0001) and PCI (1·15 min, 95% CI 0·96–1·33; p<0·0001), compared with transfemoral access. Transradial access was also associated with higher kerma-area product for diagnostic coronary angiograms (WMD, fixed effect: 1·72 Gy·cm², 95% CI –0·10 to 3·55; p=0·06), and significantly higher kerma-area product for PCI (0·55 Gy·cm², 95% CI 0·08–1·02; p=0·02). Mean operator radiation doses for PCI with basic protection were 107 µSv (SD 110) with transradial access and 74 µSv (68) with transfemoral access; with supplementary protection, the doses decreased to 21 µSv (17) with transradial access and 46 µSv (9) with transfemoral. Meta-regression analysis showed that the overall difference in fluoroscopy time between the two procedures has decreased significantly by 75% over the past 20 years from 2 min in 1996 to about 30 s in 2014 (p<0·0001). In observational studies, differences and effect sizes remained consistent with RCTs.

Interpretation Transradial access was associated with a small but significant increase in radiation exposure in both diagnostic and interventional procedures compared with transfemoral access. Since differences in radiation exposure narrow over time, the clinical significance of this small increase is uncertain and is unlikely to outweigh the clinical benefits of transradial access.

Funding None.

Introduction

Transradial access for diagnostic coronary angiography and percutaneous coronary intervention (PCI) is gaining popularity worldwide because of its proven advantages over the more traditional transfemoral access route, including reduced risk of complications associated with the access site and bleeding, improved patient comfort, early ambulation, and cost savings.[1–4] Moreover, in patients undergoing primary PCI for ST-elevation myocardial infarction, transradial access has been associated with a significant reduction in mortality and better net clinical benefits compared with transfemoral access.[2,5,6] In a large meta-analysis of more than 760 000 patients, we noted that, compared with transfemoral access, transradial access was associated with a 78% reduction in bleeding (odds ratio [OR] 0·22, 95% credible interval [CrI] 0·16–0·29) and 80% reduction in transfusions (OR 0·20, 95% CrI 0·11–0·32). Overall, mortality was also reduced by 44% with transradial access (OR 0·56, 95% CrI 0·45–0·67).[4] Despite these important advantages for patients, concerns about increased radiation exposure for both patient and operators have

partly contributed to the slow uptake of transradial access in clinical practice, especially in the USA.[7] Several observational studies and a few randomised trials have compared radiation exposure between transradial access and transfemoral access. Although the findings from some studies suggest that radiation exposure might be increased with transradial access, whether this is a real effect is unclear, because of the many limitations of observational data and the potential effect of the learning curve and operator proficiency. A large multicentre survey of more than 50 000 patients[8] even reported that the radial route was associated with lower doses of radiation than the femoral route. So far, only one large-scale randomised trial has compared radiation exposure between the radial and femoral approaches.[1] Despite this study, no global quantitative assessment of radiation exposure based on access site is available. Although data have accumulated since the inception of transradial access in 1989, the question of whether transradial access constitutes a real radiation hazard or not remains unanswered.

We therefore did a systematic review and meta-analysis with the aim of gathering data from all available randomised controlled trials and observational studies comparing radiation exposure between transradial access and transfemoral access, and assessing whether transradial access is associated with higher radiation exposure, using fluoroscopy time as a surrogate estimate of patient and operator radiation exposure, the kerma-area product as an estimate of patient exposure, and recorded operator dosimetry.

Methods

Search strategy and selection criteria

We did this systematic review and meta-analysis according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement[9] and followed a strict protocol (available on request).

We searched scientific literature databases for RCTs comparing transradial access and transfemoral access in terms of radiation exposure to the patient. We did a systematic search of PubMed, Embase, and the Cochrane Library, using various combinations of keywords such as "(trans)-radial", "(trans)-femoral", "cardiac catheterisation", "coronary", "radiation dose", "fluoroscopy", and "dose-area product" for eligible studies published from Jan 1, 1989, to June 3, 2014. Studies written in English, French, and Spanish were considered for inclusion; no other languages were allowed. We systematically searched major reviews focusing on transradial access for diagnostic and interventional procedures, and checked cross-references and cited papers to identify other relevant studies. Inclusion criteria for studies were randomised trials and observational studies comparing transradial access and transfemoral access and reporting radiation exposure as fluoroscopy time or kerma-area product, or both. We recorded operator doses whenever they were provided. We excluded studies that were only available in abstract format and studies that reported radiation exposure, but not with a transradial access versus transfemoral access design. We also excluded studies reporting ulnar access, because this procedure is rarely used.[10] Moreover, ulnar access has been shown to be inferior to radial access.[11] The subject remains, however, controversial since investigators of other studies showed a reduction in fluoroscopy time with ulnar access compared with transradial access.[10]

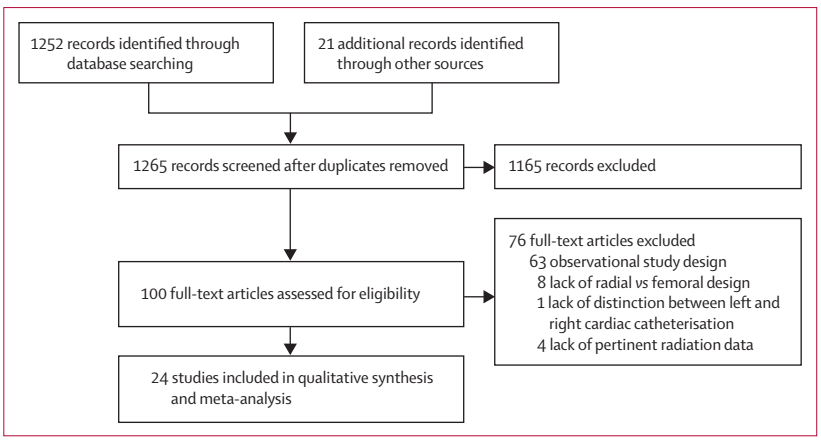

Figure 1: **Study selection**
Similar analyses were done as confirmatory data on the 63 identified observational cohort studies and are available in the appendix.

Data extraction

Three investigators (GP, SBP, and OFB) sorted the potentially relevant studies, first by title and abstract review, and then judged their eligibility by full-text review. They then extracted information about study design, sample size, demographic and procedural characteristics, access site, operator experience, and radiation exposure according to the predefined protocol, which was entered into a data sheet using a standardised protocol by two independent investigators (GP and SBP). Discrepancies were resolved by consensus between the study investigators, if necessary after contact with authors.

Outcomes

The two primary outcomes for this analysis were fluoroscopy time (min), and kerma-area product (Gy·cm²). The kerma-area product represents the absorbed radiation dose multiplied by the irradiated area. Guidelines recommend that this term should now be used instead of the more usually used term "dose-area product";[12,13] however, they are equivalent units in terms of radiological dosimetry. Fluoroscopy time is an indirect surrogate measure of radiation exposure, which has been shown to correlate closely with kerma-area product,[14] and is also a marker of procedural complexity.[15] Our secondary outcomes, pooled from individual studies when available, were operators' radiation exposure (μSv) and procedural time (min).

	Single centre *vs* multicentre	Country	Cohorts	TRA/TFA patients (n)	TRA operator experience	Inclusion criteria	Exclusion criteria
Mann et al (1996)[16]	Single centre	USA	PCI	73/75	..	Non-STEMI, new onset or unstable angina	Elective stent implantation and STEMI
Mann et al (1996)[17] (basic)	Single centre	USA	PCI and basic radiation protection	66/126	..	Elective PCI	None
Mann et al (1996)[17] (plus shield)	Single centre	USA	PCI, basic radiation protection, and floor shield	72/126	..	Elective PCI	None
ACCESS (1997)[18]	Single centre	Netherlands	PCI	279/299	..	Stable or unstable angina, single or multivessel lesions in native vessels or SVGs	Absent pulse, abnormal Allen test, failed previous access, CTO, AMI, need for IABP or TPW, ad hoc PCI after TFA DCA, and planned stenting or atherectomy
CARAFE (2001)[19]	Multicentre	France	DCA	140/70	Experienced	Normal Allen test	AMI, previous CABG, known difficulty with TFA, RHC, renal or aortic angiography, and no LV angiogram
TEMPURA (2003)[20]	Single centre	Japan	PCI	77/72	Experienced	AMI, no thrombolytic therapy, >20 years old, and normal Allen test	Culprit vessel not identified, SVG, or radial tortuosity
Reddy et al (2004)[21]	Single centre	USA	Mixed (9 PCIs)	25/50	Low (>50)	DCA referral, >18 years old, and normal Allen test	Peripheral vascular disease, previous CABG, ACS, AMI, or planned additional procedures
RADIAL-AMI (2005)[22]	Multicentre	Canada	PCI	25/25	Intermediate (>100)	Primary or rescue PCI for AMI	Cardiogenic shock, abnormal Allen test, or contraindication to GPI
Yigit et al (2006)[23]	Single centre	Turkey	DCA	75/105	Intermediate (>100)	..	Previous CABG, RHC, aortic angiography, or no LV angiogram
Lange et al (2006)[24] (DCA)	Single centre	Germany	DCA	92/103	Experienced (>1500)	Uncomplicated arterial access and procedure	Bypass graft DCA, LV cineangiography, or aortography
Lange et al (2006)[24] (PCI)	Single centre	Germany	PCI	54/48	Experienced (>1500)	Uncomplicated arterial access and procedure	Bypass graft DCA, LV cineangiography, or aortography
FARMI (2007)[25]	Single centre	France	PCI	57/57	Intermediate to experienced (>100)	ACS	Killip>II, cardiogenic shock, IABP, TPW, previous CABG, or intolerance to GPI
Achenbach et al (2008)[26]	Single centre	Germany	Mixed (79 ad hoc PCIs)	152/155	Experienced (>200)	DCA for suspected CAD, >75 years old, both TRA and TFA are feasible, availability for follow-up, normal platelet count and coagulation, and Hb >0·9 g/L	Cardiogenic shock, impaired renal function, planned right and left heart catheterisation
Brueck et al (2009)[27]	Single centre	Germany	Mixed (370 PCIs)	512/512	Experienced	DCA or PCI	Previous CABG, cardiogenic shock, known difficulty with TRA or TFA, RHC, abnormal Allen test, TPW, CKD, haemodialysis, or no experienced operators
Santas et al (2009)[28]	Single centre	Spain	Mixed (367 PCIs)	670/335	Experienced (>1000)	DCA	None
RADIAMI (2009)[29]	Single centre	Poland	PCI	50/50	Intermediate to experienced (>50–100)	Aged between 15 and 75 years, and AMI	Age >75 years, Killip III or IV, IABP, TPW, height <150 cm, or previous CABG
Rodriguez (2009)[30]	Multicentre	Spain	PCI	217/222	Experienced (>200)	AMI	Cardiogenic shock, abnormal Allen test, previous CABG, CKD, PCI in last month, or peripheral vascular disease
Hou et al (2010)[31]	Single centre	China	PCI	100/100	Experienced (>200)	AMI and of Chinese origin	Cardiogenic shock, previous CABG, abnormal Allen test, or non-palpable radial artery
RIVAL (2011)[1]	International multicentre	Canada	PCI	3507/3514 (4660 PCIs)	Experienced (>50 in last year)	ACS and normal Allen test	Cardiogenic shock, severe peripheral vascular disease, or previous CABG
RADIAMI II (2011)[32]	Single centre	Poland	PCI	49/59	Experienced	Aged between 18 and 75 years, and AMI	Age >75 years, Killip III or IV, IABP, TPW, height <150 cm, or previous CABG
Wang et al (2012)[33]	Single centre	China	PCI	60/59	Experienced (>500)	STEMI, intravenous thrombolysis <6 h from symptoms onset, and admission <12 h after intravenous thrombolysis	Contraindications to thrombolysis, previous CABG, cardiogenic shock, known difficulty with TRA or TFA, abnormal Allen test, TPW, IABP, CKD, or haemodialysis
Lange et al (2012)[34] (basic)	Single centre	Germany	DCA	51/50	Experienced	Elective, outpatient DCA, and uncomplicated procedure	Aortic valve stenosis, CABG, or difficulty with TRA or TFA
Lange et al (2012)[34] (plus shield)	Single centre	Germany	DCA	56/53	Experienced	Elective, outpatient DCA, and uncomplicated procedure	Aortic valve stenosis, CABG, or difficulty with TRA or TFA

(Table 1 continues on next page)

	Single centre *vs* multicentre	Country	Cohorts	TRA/TFA patients (n)	TRA operator experience	Inclusion criteria	Exclusion criteria
(Continued from previous page)							
Jolly et al (2013)[35] (PCI)	International multicentre	Canada	PCI	2249/2295†	Experienced (>50 in last year)	ACS and normal Allen test	Cardiogenic shock, severe peripheral vascular disease, and previous CABG
Jolly et al (2013)[35] (DCA)	International multicentre	Canada	DCA	602/594‡	Experienced (>50 in last year)	ACS and normal Allen test	Cardiogenic shock, severe peripheral vascular disease, and previous CABG
RADIAL-CABG (2013)[36] (PCI)	Single centre	USA	PCI	24/30	Experienced (>1000)	Previous CABG	STEMI, abnormal Allen test, known difficulty with TRA or TFA, or age >90 years
RADIAL-CABG (2013)[36] (DCA)	Single centre	USA	DCA	63/63	Experienced (>1000)	Previous CABG	STEMI, abnormal Allen test, known difficulty with TRA or TFA, or age >90 years
STEMI-RADIAL (2014)[6]	International multicentre	Czech Republic, Canada	PCI	348/359	Experienced (>200 in last year)	Acute STEMI	Cardiogenic shock, previous aortobifemoral bypass, abnormal Allen or Barbeau test, oral anticoagulants, or absence of bilateral radial or femoral pulses
OCEAN RACE (2014)[37]	Single centre	Poland	PCI	52/51	(>200/year)	Age >18 years, STEMI	INR >1·4, platelets <100 000/μL, previous CABG, known vascular access difficulties, or active bleeding, peptic ulcer, dialysis, liver failure, uncontrolled hypertension, cardiogenic shock, or low compliance

TRA=transradial access. TFA=transfemoral access. PCI=percutaneous coronary intervention. AMI=acute myocardial infarction. CTO=chronic total occlusion. IABP=intra-aortic balloon pump. TPW=temporary pacing wire. DCA=diagnostic coronary angiogram. CABG=coronary artery bypass grafting. RHC=right heart catheterisation. LV=left ventricle. SVG=saphenous vein graft. ACS=acute coronary syndrome. GPI=glycoprotein 2B/3A inhibitors. CAD=coronary artery disease. Hb=haemoglobin. CKD=chronic kidney disease. STEMI=ST segment elevation myocardial infarction. INR=international normalised ratio. *Author name, publication year, and reference number. †Of 2249 patients with TRA and PCI, only 470 had air kerma data, and only 694 had kerma-area-product data. Similarly, of 2295 patients with TFA and PCI, only 476 had air kerma data, and only 698 had kerma-area-product data. ‡Of 602 patients with TRA and DCA, only 248 had air kerma data, and only 438 had kerma-area-product data. Similarly, of 594 patients with TFA and PCI, only 251 had air kerma data, and only 425 had kerma-area-product data.

Table 1: **Description of 24 randomised controlled trials* included in the meta-analysis**

We subsequently did sensitivity analyses for the primary radiation exposure outcomes. Our prespecified subgroups were based on the type of intervention (diagnostic coronary angiograms *vs* PCI). Although some investigators reported specified cutoffs for various levels of operator experience, we reported operators' skills in transradial access as per the investigators' own definition (experienced, intermediate, and low experience; table 1). We also did a sensitivity analysis by reviewing all randomised studies comparing left radial access with right radial access using fluoroscopy time as a surrogate of radiation exposure (appendix).

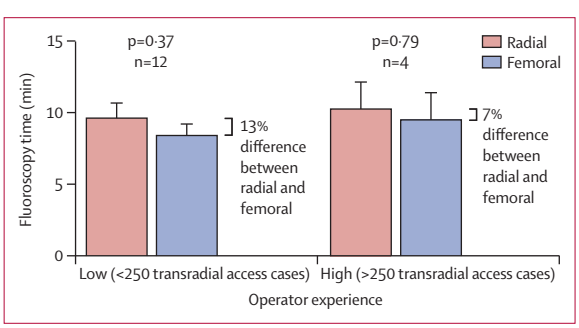

Figure 2: **Fluoroscopy time in PCI by operator experience**
PCI=percutaneous coronary intervention. TRA=transradial access.

See **Online** for appendix

Statistical analysis

We did the main analyses for data drawn from randomised trials. We did similar analyses of observational studies as confirmatory data (appendix). Reviewers did data validity assessments in duplicate. The absolute numbers for each outcome of interest in each study were extracted for transradial access and transfemoral access groups, and entered into the Cochrane Collaboration Review Manager (RevMan) software program, version 5.1.20. We summarised the data as the weighted mean difference (WMD) of continuous variables with 95% CIs, and combined them using both fixed-effects and random-effects models with inverse variance weighting. We did sensitivity analyses that subsequently removed a randomised study by Achenbach and colleagues,[26] which was assigned the largest weight in the random model, and the randomised study by Michael and colleagues,[36] which included patients who had undergone previous coronary arterial bypass grafting (CABG). Sensitivity analyses aimed to assess the effect of the remaining studies without the larger one's effect. When SDs were missing, or data were expressed as medians (IQR), we contacted the authors to obtain means and SDs. Hypothesis testing was two-tailed and p less than 0·05 was deemed significant. We assessed heterogeneity across studies with Cochran's Q statistic (χ^2), deeming p less than 0·10 as significant. We also assessed heterogeneity with the I^2 test, for which an I^2 value of less than 25% was judged as showing low heterogeneity, 25–50% was moderate, and greater than 50% was substantial. We did meta-regression analysis using a fixed-effect model in Comprehensive Meta-Analysis software version 10. We used the Cochrane Handbook version 5.1.0[38] for methodological guidance. The quality of the methods in

	Mann et al (1996)[16]	Mann et al (1996)[17] basic	Mann et al (1996)[17] plus shield	ACCESS (1997)[18]	CARAFE (2001)[19]	TEMPURA (2003)[20]	Reddy et al (2004)[21]	RADIAL-AMI (2005)[22]	Yigit et al (2006)[23]	Lange et al (2006)[24]	FARMI (2007)[25]	Achenbach et al (2008)[26]	Brueck et al (2009)[27]
Procedure type	PCI	PCI	PCI	PCI	DCA	PCI	Mixed data	PCI	DCA	Mixed data	PCI	PCI	Mixed data
Total number of patients	148	192	198	578	210	149	75	50	180	297	114	307	1024
Radial	73	66	72	279	140	77	25	25	75	146	57	152	512
Femoral	75	126	126	299	70	72	50	25	105	151	57	155	512
Males													
Radial	53 (73%)	..	..	221 (79%)	109 (78%)	62 (81%)	16 (64%)	19 (76%)	45 (60%)	113 (78%)	49 (86%)	70 (46%)	292 (57%)
Femoral	52 (69%)	..	..	220 (74%)	54 (77%)	59 (82%)	29 (58%)	25 (100%)	65 (62%)	115 (76%)	47 (83%)	68 (44%)	309 (60%)
Age (years)													
Radial	64	..	..	61 (11)	61 (11)	66 (12)	58 (2)	52 (48–60)	58 (9)	60 (10)	60 (12)	78 (3)	63 (12)
Femoral	62	..	..	62 (10)	65 (13)	67 (10)	63 (3)	58 (49–72)	59 (15)	61 (10)	58 (13)	78 (3)	64 (12)
Body-mass index (kg/m^2)													
Radial	..	..	..	26	..	24	28	..	28 (4)	..	28	..	28 (6)
Femoral	..	..	..	26	..	24	30	..	27 (4)	..	27	..	29 (4)
Previous CABG													
Radial	8 (11%)	..	..	28 (9%)	..	..	0	..	..	..	0	12 (8%)	..
Femoral	10 (13%)	..	..	17 (6%)	..	..	0	..	..	..	0	19 (12%)	..
Procedural time (min)													
Radial	38 (3)	45	44	40 (24)	13 (7)	44 (18)	23 (4)	49 (40–61)	16 (6)	..	45 (16)	..	40 (24–51)
Femoral	36 (2)	..	..	38 (24)	11 (3)	51 (21)	25 (4)	47 (39–64)	9 (3)	..	39 (19)	..	37 (20–49)
Fluoroscopy time (min)													
Radial	13 (1)	19	18	13 (11)	4 (3)	15 (8)	6 (1)	11 (8–15)	4 (2)	3 (2)/11 (8)*	13 (9)	6 (6)	9 (4–11)
Femoral	12 (1)	16	16	11 (10)	3 (2)	16 (8)	7 (2)	9 (7–17)	2 (1)	1 (1)/10 (7)*	8 (6)	5 (4)	6 (2–8)
Kerma-area product (Gy·cm^2)													
Radial	..	..	..	..	..	..	..	..	..	15 (8)/46 (29)*	..	4 (2)	38 (21)
Femoral	..	..	..	..	..	..	..	..	..	13 (9)/51 (29)*	..	3 (2)	37 (20)

(Table 2 continues on next page)

the included studies was assessed with the Cochrane Collaboration's method for assessing risk of bias for the RCTs, and with the Newcastle-Ottawa Scale for the observational cohort studies. If the risk of bias was too great for a particular study, whether that study should be included in our analysis was discussed among the co-investigators. We assessed publication bias by visual inspection of funnel plots for fluoroscopy time and kerma-area product, and by computation of Egger's test statistic (one-sided and two-sided p values; data and figures in the appendix).

Role of the funding source

The study received no funding. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

From an initial screen of 1265 records, we reviewed and included 24 RCTs undertaken between 1995 and 2014 in our meta-analysis, which included data for 19 328 patients in 11 countries (figure 1). 18 studies were single-centred, and six were multicentred (table 1). Most of the studies were small—only four enrolled more than 1000 patients. The level of operator skill was heterogeneous across the 24 trials, with some trials done by highly experienced radial operators, but others only required that operators had done more than 50 cases of transradial access in the year before starting enrolment (table 1). Overall, although not significant, differences in radiation exposure between transradial access and transfemoral access were about 50% lower in experienced operators

	Santas et al (2009)[28]	RADIAMI (2009)[29]	Rodriguez (2009)[30]	Hou et al (2010)[31]	RIVAL (2011)[1]	RADIAMI II (2011)[32]	Wang et al (2012)[33]	Lange et al (2012)[34] basic	Lange et al (2012)[34] plus shield	Jolly et al (PCI) (2013)[35]	RADIAL-CABG (2013)[36]	STEMI-RADIAL (2014)[6]	OCEAN RACE (2014)[37]
(Continued from previous page)													
Procedure type	DCA	PCI	PCI	PCI	Mixed data	PCI	PCI	DCA	DCA	Mixed data	Mixed data	PCI	PCI
Total number of patients	1005	100	439	200	7021	108	119	101	109	2569	128	707	103
Radial	670	50	217	100	3507	49	60	51	56	1290	64	348	52
Femoral	335	50	222	100	3514	59	59	50	53	1279	64	359	51
Males													
Radial	464 (69%)	35 (52%)	184 (85%)	72 (72%)	2599 (74%)	32 (65%)	52 (87%)	37 (73%)	41 (73%)	914 (71%)	64 (100%)	262 (75%)	..
Femoral	239 (71%)	33 (49%)	186 (84%)	69 (69%)	2561 (73%)	37 (63%)	49 (83%)	30 (60%)	39 (74%)	931 (73%)	64 (100%)	284 (79%)	..
Age (years)													
Radial	66 (12)	60 (9)	60 (13)	65 (8)	62 (12)	62 (9)	60 (12)	63 (9)	64 (10)	63 (12)	65 (6)	63 (12)	61 (50–72)
Femoral	66 (11)	59 (9)	62 (12)	66 (8)	62 (12)	58 (10)	60 (11)	65 (12)	66 (10)	63 (12)	67 (6)	62 (11)	63 (50–75)
Body-mass index (kg/m^2)													
Radial	..	28	28 (4)	..	..	29	27 (3)	..	..	28 (5)	32 (6)	29 (4)	26 (22–30)
Femoral	..	30	28 (4)	..	..	28	26 (3)	..	..	28 (5)	30 (5)	28 (4)	27 (23–31)
Previous CABG													
Radial	48 (7%)	0	0	0	79 (2%)	0	0	0	0	31 (2%)	64 (100%)	3 (1%)	0
Femoral	18 (8%)	0	0	0	75 (2%)	0	0	0	0	32 (3%)	64 (100%)	3 (1%)	0
Procedural time (min)													
Radial	28 (12)	58 (18)	..	37 (7)	35 (22–50)	54 (21)	46 (13)	..	..	..	34 (15)/41 (20)*	49 (20)	..
Femoral	29 (9)	55 (18)	..	36 (8)	34 (22–50)	47 (20)	48 (19)	..	..	..	22 (7)/45 (27)*	49 (18)	..
Fluoroscopy time (min)													
Radial	5 (5)	11 (6)	14 (12)	12 (2)	9 (6–15)	8 (3)	14 (6)	3 (2)	3 (1)	5 (6)/15 (27)*	13 (6)/11 (7)*	8 (5)	3 (2)
Femoral	4 (3)	11 (6)	13 (15)	11 (2)	8 (5–13)	7 (3)	12 (6)	2 (1)	2 (1)	4 (5)/12 (14)*	9 (5)/12 (9)*	8 (6)	3 (2)
Kerma-area product (Gy·cm^2)													
Radial	..	..	..	..	..	..	..	23 (14)	24 (14)	41 (33)/90 (80)*	..	..	..
Femoral	..	..	..	..	..	..	..	24 (16)	20 (13)	40 (32)/87 (75)*	..	..	..

Data are n (%), mean (SD), or median (IQR), when available. PCI=percutaneous coronary intervention. DCA=diagnostic coronary angiogram. CABG=coronary artery bypass grafting. ..=not applicable. *DCA/PCI data.

Table 2: **Baseline and procedural characteristics of the trials**

(>250 cases of transradial access) than in less experienced operators (<250 cases of transradial access; figure 2). In four of the studies, data for diagnostic procedures could not be distinguished from the data for interventional procedures. These studies were included in the PCI group for the meta-analysis. 11 studies excluded patients with cardiogenic shock.

When studies presented data for both diagnostic and interventional procedures, each subgroup was presented separately and identified with its respective procedure type in the relevant tables and figures. We further identified 12 randomised and four observational studies that compared left radial and right radial access. Left radial access was associated with a reduction in

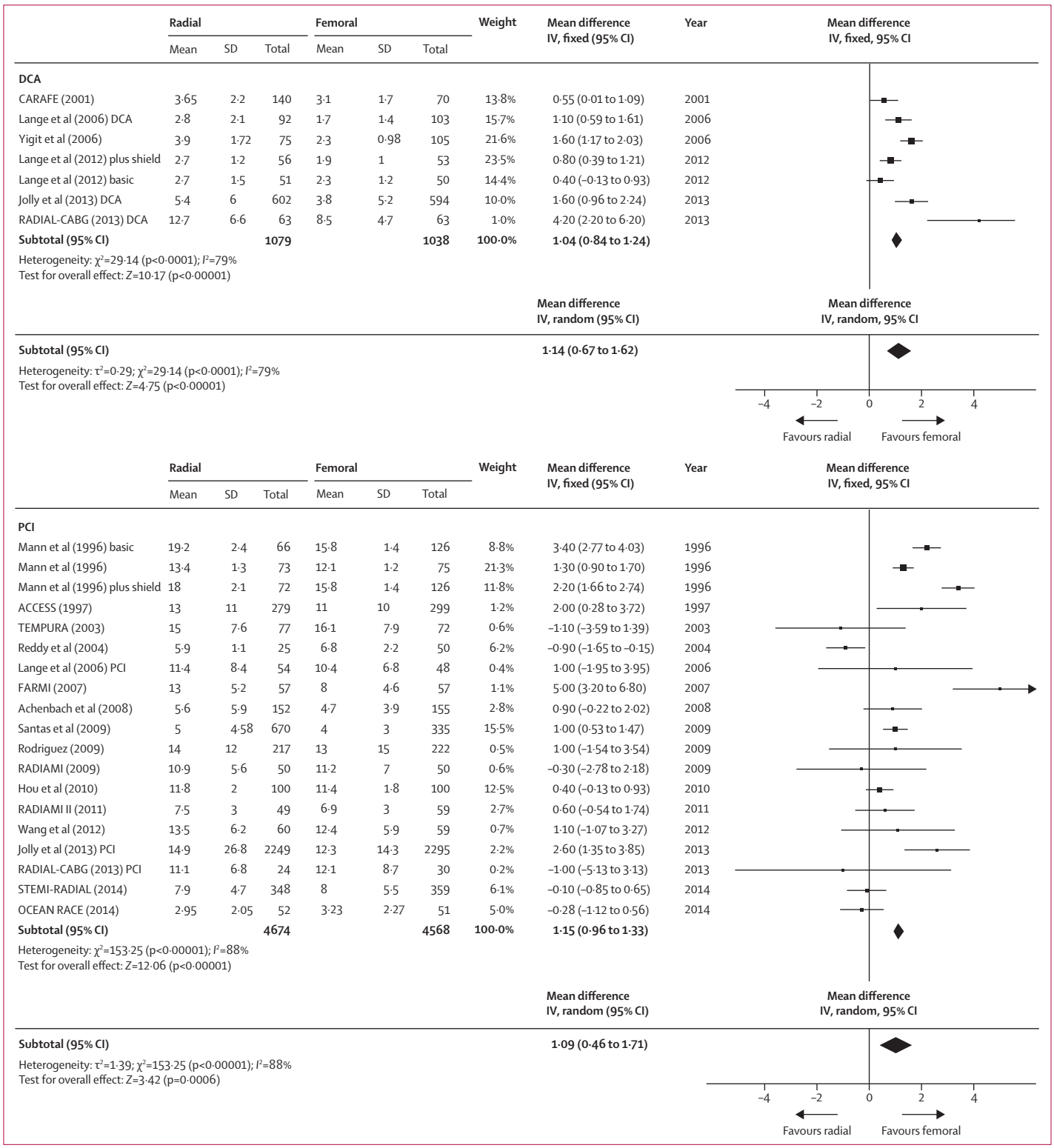

***Figure 3*: Forest plot of fluoroscopy time in diagnostic coronary angiograms and PCI**
DCA=diagnostic coronary angiogram. PCI=percutaneous coronary intervention. IV=inverse variance. For each estimate, the shaded area represents the weight of the estimate in the model.

fluoroscopy time of 0·35 min WMD (95% CI 0·02–0·68, p=0·04) (appendix).

Patient and procedural characteristics were well matched between the radial and femoral groups (table 2). The mean age of the patients was 63 years (SD 4) and 11 370 (73%) were men. Mean procedural time, reported in 18 studies, was 38 min (SD 12) for transradial access, and 35 min (13) for transfemoral access. We identified evidence of selection bias in nine studies (appendix), one at risk of attrition bias,[22] but there was no evidence of publication bias significantly affecting the results (appendix). Fluoroscopy time, which was reported in all studies, was longer in transradial access procedures than in transfemoral procedures, both for diagnostic coronary angiograms and PCI (figure 3). The meta-analysis of randomised data showed a WMD (fixed effect) of 1·04 min (95% CI 0·84–1·24; p<0·0001) for diagnostic coronary angiograms and 1·15 min (95% CI 0·96–1·33; p<0·0001) for PCI, both in favour of transfemoral access. Even after removal of the RADIAL-CABG study by Michael and colleagues,[36] our sensitivity analysis remained in favour of transfemoral access both for diagnostic coronary angiograms (WMD, fixed effect 1·01 min [95% CI 0·81–1·21]; p<0·0001) and PCI (1·15 min [95% CI 0·96–1·34]; p<0·0001). Our meta-regression analysis of differences in fluoroscopy time from 1996 up to now for RCTs of diagnostic and interventional procedures (figure 4) showed that the overall difference between transradial access and transfemoral access has decreased significantly by 75%, from 2 min in 1996 to around 30 s in 2014 (p<0·0001).

Five studies reported kerma-area product (figure 5). This variable was greater in the transradial access group for diagnostic coronary angiograms procedures (WMD, fixed effect 1·72 Gy·cm² [95% CI –0·10 to 3·55]) but not significantly (p=0·06). For PCI procedures, transradial access was associated with a significantly greater kerma-area product than transfemoral access (WMD, fixed effect 0·55 Gy·cm² [95% CI 0·08–1·02]; p=0·02). After removal of the study by Achenbach and colleagues,[26] the results from the sensitivity analysis showed that kerma-area product was not significantly lower with transfemoral access for PCI procedures (WMD 0·81 Gy·cm² [95% CI –1·54 to 3·15]; p=0·50).

Four of the included studies reported operator doses per procedure (table 3).[17,24,34,36] For PCI with basic radiation protection, the mean operator dose was 107 µSv (SD 110) for transradial access and 74 µSv (68) for transfemoral access. When supplementary radiation protection was added (movable floor shield or pelvic lead shield), the mean operator dose fell to 21 µSv (SD 17) for transradial access and 46 µSv (9) for transfemoral access.[17,34]

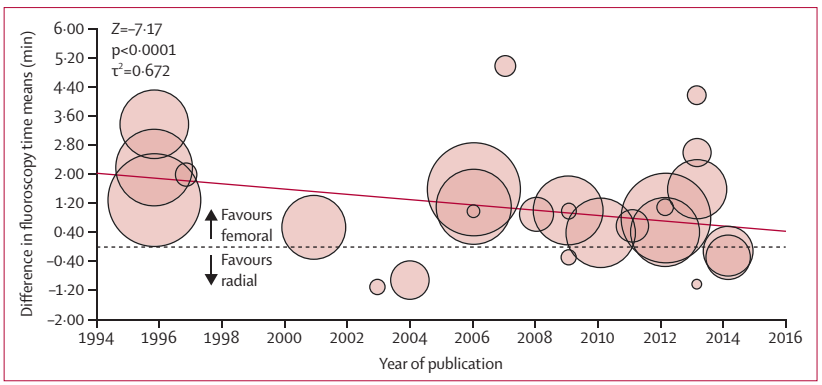

Figure 4: **Meta-regression analysis of effects of time on radiation exposure**
Data expressed as a difference in fluoroscopy time means. Circles represent each of the 24 studies included in the meta-analysis. Z=measure of overall effect. τ^2=estimate of the between-study variance.

Discussion

Although observational and randomised data for radiation dosimetry in cardiac catheterisation have been accumulating since 1989, whether transradial access is associated with a clinically significant increase in patient and operator radiation exposure compared with transfemoral access is unclear. Radiation exposure in interventional cardiology is of the utmost importance, because low but frequent doses of ionising radiation can cause effects including skin injuries, premature cataract development, and increased lifetime risk of cancer.[39,40]

For this systematic review and meta-analysis, we obtained all evidence so far published in RCTs on the effect of access site on radiation exposure from 11 countries and 19 328 patients. We noted that transradial access, compared with transfemoral access, was associated with a small increase in fluoroscopy time. The magnitude of this effect was about one to two extra minutes of fluoroscopy. Moreover, a clear evolution in this difference was evident, with more recent studies showing a much smaller gap (about 30 s) in fluoroscopy time. This evolution could be attributable to some factors of contemporary practice such as dedicated transradial devices and techniques, better imaging equipment, and a general increase in operator skill. Indeed, no differences are apparent in either patient or operator radiation exposure when procedures are done by expert operators.[35,41]

For patient radiation doses expressed with kerma-area product, we noted higher values with transradial access for diagnostic coronary angiograms, and a significant increase with transradial access for PCI of 0·5–2·0 Gy·cm². These differences are small and contribute to an increased dose equivalent to that provided by five chest radiographs (0·5–2·0 Gy·cm², around 0·11–0·44 mSv [conversion factor 0·18–0·22 mSv/Gy·cm² for the thoracic region]).[42] In other words, considering an additional lifetime cancer risk of 2·5%/Sv (1:40 000/mSv)[43] between age 40 and 60 years, radial access would be associated with an increased lifetime cancer risk between 1:90 900 and 1:363 000. This magnitude of change is similar to the radiation exposure received by airline passengers completing two return transatlantic flights.[44] Much larger differences in radiation exposure have been recorded

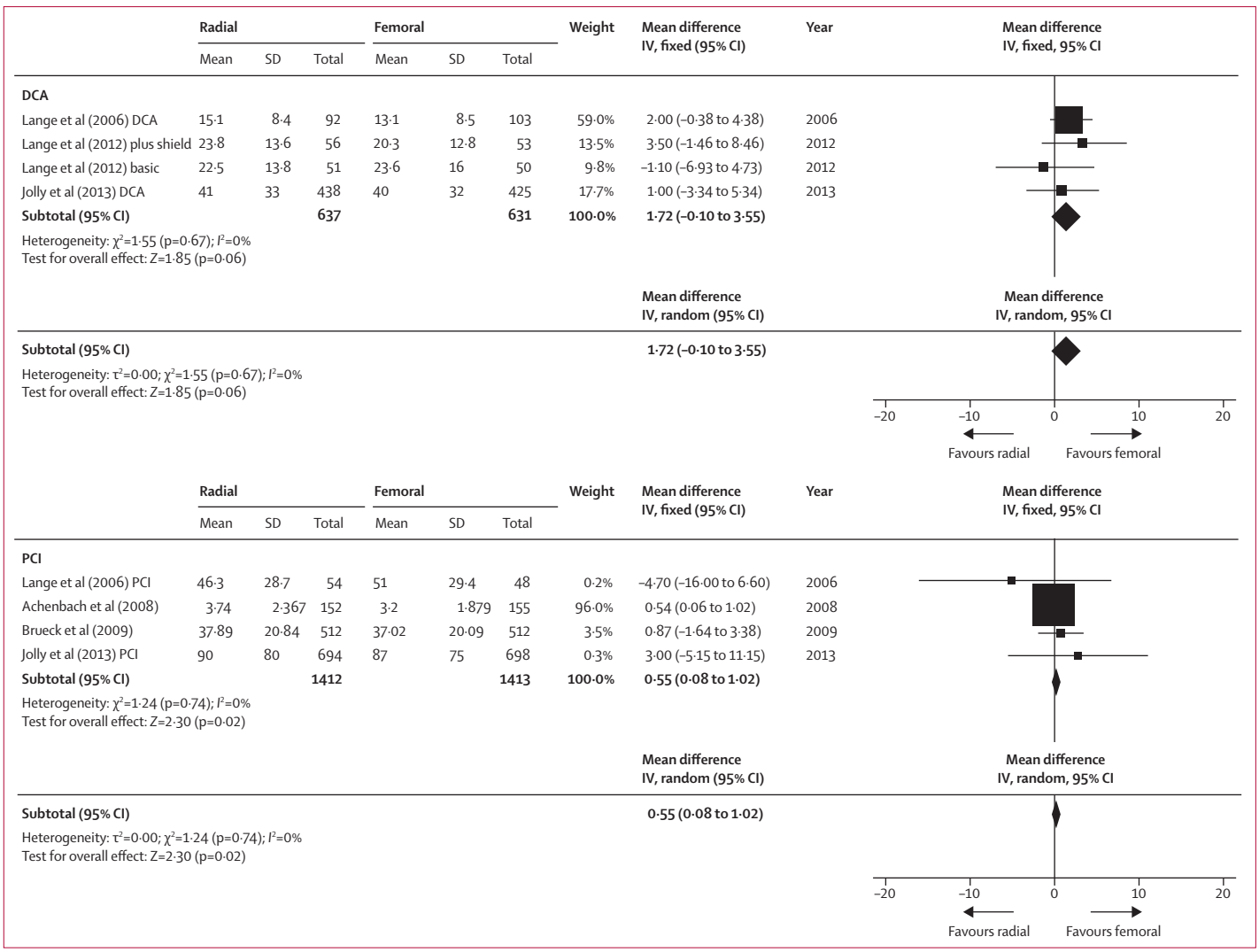

Figure 5: **Forest plot of kerma-area product for diagnostic coronary angiograms and PCI**
DCA=diagnostic coronary angiogram. PCI=percutaneous coronary intervention. IV=inverse variance. For each estimate, the shaded area represents the weight of the estimate in the model.

between operators, mediated by variation in radiation-protection practices. The International Commission on Radiological Protection has published a position statement on radiation exposure, in which they recommend a kerma-area product of less than 500 Gy·cm².[45] Thus, the small increase attributable specifically to transradial access represents only 6% of the total dose during diagnostic coronary angiogram procedures, and only 3% of the total dose during PCI. Nowadays, mean reported kerma-area products are between 16 and 106 Gy·cm² for diagnostic coronary angiograms and between 34 and 109 Gy·cm² for PCI.[46] Therefore, our data suggest that the differences of doses for diagnostic coronary angiograms and PCI attributed to access site can be regarded as low compared with other factors.

Data for operator dosing are based on only a few studies, and clearly, operator dose is highly dependent on the specific protection protocol used. When optimum radiation protection is practised, an increase in operator dose with transradial access is not evident.[41] The radial-related radiation exposure variables are evolving over time, are highly related to operator-dependent factors, and should not represent a substantial barrier to widespread uptake of transradial access. These variables are, however, a reminder of the importance of good radiation-protection practice in all cardiac procedures, especially during the operator's learning curve.[47] One report encouraged operators to pursue proper education in the radiological specialty, and to adopt justification and optimisation of fluoroscopy use in their daily practice.[48] With optimum radiation shielding, transradial access has been associated with a 15% reduction in radiation dose compared with transfemoral access.[49] Novel protocols have been described with modern equipment and radioprotection devices, and they suggest a dose reduction of up to nearly 50% during both diagnostic coronary angiograms and PCI.[50,51] These

	Mann et al (1996)[17]		Lange et al (2006)[24]		Lange et al (2012)[34]		RADIAL-CABG (2013)[36]	
	PCI*	PCI†	DCA	PCI	DCA*	DCA‡	DCA	PCI
Total number of patients	192	198	195	102	101	109	126	54
Radial	66 (34%)	72 (36%)	92 (47%)	54 (53%)	51 (51%)	56 (51%)	63 (50%)	24 (45%)
Femoral	126 (66%)	126 (64%)	103 (53%)	48 (47%)	50 (49%)	53 (49%)	63 (50%)	30 (55%)
Operator dose (μSv)								
Radial	135 (21)	33 (23)	64 (55)	166 (188)	21 (14)	9 (5)	44 (38)	21 (18)
Femoral	88 (13)	88 (13)	32 (39)	110 (115)	15 (10)	3 (3)	21 (21)	23 (25)
Fluoroscopy time (min)								
Radial	19	18	3 (2)	11 (8)	3 (2)	3 (2)	13 (6)	11 (7)
Femoral	16	16	2 (1)	10 (7)	2 (1)	2 (1)	9 (5)	12 (9)
Kerma-area product (Gy·cm^2)								
Radial	..	..	15 (8)	46 (29)	23 (14)	24 (14)	..	..
Femoral	..	..	13 (9)	51 (29)	24 (16)	20 (13)	..	..

Data are n (%) or mean (SD), when available. PCI=percutaneous coronary intervention. DCA=diagnostic coronary angiogram. ..=not applicable. *Basic radiation protection (lead aprons, thyroid collars, lead glasses, and overhead and side table lead curtain shields). †Basic radiation protection plus movable floor shield. ‡Basic radiation protection plus pelvic lead shield.

Table 3: **Operator radiation exposure per procedure**

radiation reduction protocols are easy to put in place and are very efficient in dose minimisation both for operators and patients. Operators' occupational doses are also related to patients' radiation exposure, and thus keeping the focus on the "as low as reasonably achievable" (ALARA) principle for radiation doses and exposure would be beneficial for both, especially in consideration of the long-term exposure for high-volume operators.[52]

Transradial access is now widely accepted as a serious alternative to the traditional transfemoral route, and is superior in many circumstances. Findings from several trials have shown that transradial access reduced complications of access site and bleeding compared with transfemoral access, with this effect translating into a survival benefit in some patient subgroups.[1,2,53] Additional advantages of transradial access include early ambulation, patient comfort, and cost savings.[4,54,55] The issue of increased radiation exposure with transradial access, which is probably related to factors such as operator skill, quality of equipment, procedure type, and patient characteristics, has been frequently discussed and could lead to concern amongst interventional cardiologists, slowing the uptake of this procedure and exposing patients to an unnecessary risk of access-site complications.[56] The findings of our meta-analysis provide the largest insight available up to now, and should reassure operators contemplating adopting transradial access as a default access site.

We acknowledge that our study had some limitations, especially because systematic reviews and meta-analyses themselves are subject to various biases. To address this issue and minimise the risk, we followed strict methods. Heterogeneity was evident among studies assessing radiation exposure in a cardiac catheterisation setting, especially regarding operator experience with transradial access. Up to now, no consensus has been reached on how to define various levels of radial skill (low, intermediate, or high), making any quantitative comparisons between studies impossible. Moreover, some of the heterogeneity in the effect of the arterial route could be attributable to differences in the overall level of radiation. This possibility remains to be explored.

Few data were presented about the operator's radiation exposure. Since it was a secondary outcome in this patient-oriented meta-analysis, we included operator radiation dosimetry only when it was provided. This outcome is, however, an interesting and important field that should be explored in further studies.

In conclusion, transradial access was associated with a small but statistically significant increase in radiation exposure in both diagnostic and interventional procedures, compared with transfemoral access. Because differences in radiation exposure narrow with operator experience, the clinical significance of this small increase is uncertain and is unlikely to outweigh the clinical benefits of transradial access in contemporary practice. Nonetheless, and since transradial access use is increasing in popularity worldwide, operators and institutions should ensure that adequate measures are taken to continually minimise radiation exposure by enhancing training and adhering to the ALARA principle, while simultaneously improving patients' clinical outcomes.

Contributors

GP, SBP, and OFB conceived the research project, coordinated the contributors, selected the studies, designed and executed the analyses, interpreted the findings, wrote the first draft, and revised subsequent drafts. They also had final responsibility for decision to publish. JN and SJ contributed to analysis design, interpretation of findings, manuscript preparation, and revision of drafts. SB contributed to analysis design, interpretation of findings, and manuscript preparation. SVR, IA, TP and JBD contributed to interpretation of findings and manuscript preparation. All authors participated in drafting the manuscript and ensured the validity and integrity of the data and analyses.

Declaration of interests
We declare no competing interests.

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